# IAP6 Rec'd PCT/PTO 08 MAY 2007

٦	ΓRAN	ISMITTAL LETTER TO THE UNIT OFFICE (I CONCERNING A SUBMISS	CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER: 08178.0031					
			U.S. APPLICATION NO. if known, see 37 CFR 1.5( 10/578,077					
		ATIONAL APPLICATION NO. 2004/016805	PRIORITY DATE CLAIMED November 5, 2003					
	TITLE OF INVENTION METHOD AND KIT FOR ESTIMATING SIDE EFFECT BY PACLITAXEL THERAPY							
	APPLICANT(S) FOR DO/EO/US  Veshio MIVI Masseli MATSIJIBA Minery ISOMURA Seteshi MIVATA Masselia VOSUIMOTO and Tatava NODA							
Yoshio MIKI, Masaaki MATSUURA, Minoru ISOMURA, Satoshi MIYATA, Masataka YOSHIMOTO, and Tetsuo NODA  Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:								
1.			concerning a filing under 35 U.S.C 371.					
2.	Ø	This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.						
3.	0	This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.						
4.		The US has been elected (Article 31)						
5.		A copy of the International Applicatio						
		. 5	ed only if not communicated by the International	Bureau).				
			by the International Bureau.					
	_	c. is not required, as the application was filed with the United States Receiving Office (RO/US).						
6.		An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).						
		a. is attached hereto.	W. J. J. 2511.0.0.451/.NV					
	,	b. has been previously submitted under 35 U.S.C. 154(d)(4).						
7.		Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).						
		a. are attached hereto (required only if not communicated by the International Bureau).						
			by the International Bureau.					
			vever, the time limit for making such amendments	s has NOT expired.				
	_	d. have not been made and						
8.	0		e amendments to the claims under PCT Article 1	9 (35 U.S.C. 371 (c)(3)).				
9.	⊠	An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).						
10.		An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).						
Iten	ns 11 1	to 20 below concern document(s) or	Information included:					
11.		Information Disclosure Statement under 37 CFR 1.97 and 1.98						
12.		An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.						
13.		A preliminary amendment.						
14.		An Application Data Sheet under 37 CFR 1.76.						
15.		A Substitute specification.						
16.		A power of attorney and/or change of address letter.						
17.		A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825,						
18.		A second copy of the published Inter	national Application under 35 U.S.C. 154 (d)(4).					
19.		A second copy of the English langua	ge translation of the international application 35 L	J.S.C. 154 (d)(4).				
20.	⊠	Other items or information:						
		a. ☐ Copy of cover page of International Publication No. WO b. ☒ Copy of Notification of Missing Requirements. c. ☐						

	10/578,0	ICATION NO. (if known, see 37 CFR 1.5)  INTERNATIONAL APPLICATION NO.  PCT/JP2004/016805			ATTORNEY'S DOCKET NUMBER 08178.0031			
		The following fees ha	ve been submitted:				CALCULATIONS	PTO Use
	21. BASIC NATIONAL FEE (37 CFR 1.492(a)):\$300.00					\$	Only	
	22. Examination fee (37CFR 1.492(c))  If the Written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					\$	-	
-	23. Search fee (37 CFR 1.492(b))  If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					\$		
•				1, 22 and 23 =			\$	
	☐ Addit	listing in compliance velectronic medium) (3	with 37 CFR 1.821(c) or (e)	r over 100 sheets (excluding sor computer program listing in paper or fraction thereof.	equence an			
		Total Sheets	Extra Sheets	Number of each additional thereof (round up to a who		Rate		
		- 100 =	/50=			x \$250.00	\$	
	Surcharge commend	e of \$130.00 for furnishing tement of the national sta	g any of the search fee, exa age (37 CFR 1.492(h)).	amination fee, or the oath or de	eclaration after the da	ate of	\$130.00	
		CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			
	Total Clai	ms	- 20 :		× \$50.0	x \$50.00		
	Independ	ent Claims	-3 :	=	x \$200.00		\$	
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) +\$360.00				\$			
	TOTAL OF ABOVE CALCULATIONS =					\$130.00		
	☐ Applic	Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					\$	
		SUBTOTAL  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE					\$130.00	
							\$	
							\$130.00	
	Fee for re cover she	for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate ar sheet (37 CFR 3.28, 3.31). \$40.00 per property.				ropriate +	\$	
5/10/20	7 MKAYPI	MKAYPAGH 00000037 10578077 TOTAL FEES ENCLOSED =				\$130.00		
01 FC:16	.7		130.00 OP				Amount to be refunded:	\$
							charged:	\$
	a. ⊠	A check in the amount of	f \$ 130.00	to cover the above fe	es is enclosed.			
		Please charge my Depos A duplicate copy of this s	sit Account Nosheet is enclosed.	in the amount of \$ to cover the above fees.				
	<ul> <li>c.</li></ul>					any overpaym	ent to Deposit Accou	ınt
						mation should not b	e included	
		NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 to restore the International Application to pending status.				R 1.137(a) or	(b)) must be filed ar	d granted
	SEND ALL CORRESPONDENCE TO:							
	Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 901 New York Avenue, N.W. Washington, DC 20001-4413  Ernest F, Chapman Reg. No. 25,9			961				
	DATED: May 8, 2007							

#### TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED CUSTOMER NO. 22,852 OFFICE (DO/EO/US) ATTORNEY'S DOCKET NUMBER: **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** 08178.0031 U.S. APPLICATION NO. if known, see 37 CFR 1.5( 10/578.077 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/JP2004/016805 November 5, 2004 November 5, 2003 TITLE OF INVENTION METHOD AND KIT FOR ESTIMATING SIDE EFFECT BY PACLITAXEL THERAPY APPLICANT(S) FOR DO/EO/US Yoshio MIKI, Masaaki MATSUURA, Minoru ISOMURA, Satoshi MIYATA, Masataka YOSHIMOTO, and Tetsuo NODA Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U.S.C 371. 1. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 3. (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371 (c)(2)). is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. h. is not required, as the application was filed with the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. a. has been previously submitted under 35 U.S.C. 154(d)(4). b. 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)). are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. h have not been made; however, the time limit for making such amendments has NOT expired. C. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 8. An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). Ø 9. An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371 (c)(5)). Items 11 to 20 below concern document(s) or Information included: Information Disclosure Statement under 37 CFR 1.97 and 1.98 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. 14. An Application Data Sheet under 37 CFR 1.76. 15. A Substitute specification. 16. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825. 17 🗆 18. A second copy of the published International Application under 35 U.S.C. 154 (d)(4). 19. A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4). 20. Other items or information: Copy of cover page of International Publication No. WO a. $\boxtimes$ Copy of Notification of Missing Requirements. b. C. d.

LIC ADDI (ATTOLING (FL.)							
U.S. APPLICATION NO. (if knows	n, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.			ATTORNEY'S DOCKET NUMBER		
10/578,077	I	PCT/JP2004/016805			08178.0031		
The following fees ha	ive been submitted:				CALCULATIONS	PTO Use Only	
21. BASIC NATIONAL F	EE (37 CFR 1.492(a)):		\$300.00		\$	·	
22. Examination fee (37C	FR 1.492(c))						
If the Written opinion prepared by	ISA/US or the International p	oreliminary examination repor	t prepared		\$		
All other situations	aims satisfy provisions of PC	T Article 33(1)-(4)	\$0 \$200				
23. Search fee (37 CFR 1 If the written opinion of the ISA/US IPEA/US indicates all claim Search fee (37 CFR 1.445(a)(2)) International Searching Au International Search Report prepa previously communicated t All other situations	\$						
	TOTAL of 21	i, 22 and 23 =			\$		
Additional fee for specification listing in compliance electronic medium) (3 The fee is \$250 for each of the fee i							
Total Sheets	Extra Sheets	Number of each additional thereof (round up to a who		Rate			
- 100 =	/50=			x \$250.00	\$		
Surcharge of \$130.00 for furnishin commencement of the national state.	age (37 CFR 1.492(h)).	mination fee, or the oath or do	aclaration after the da	ate of	\$130.00		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE				
Total Claims	- 20 =		x \$50.0		\$		
Independent Claims  MULTIPLE DEPENDENT CLAIM	-3 =	<u> </u>	x \$200.0		\$		
MULTIPLE DEPENDENT CEATING	(S) (II applicable)		+\$360.0	·	\$		
			L OF ABOVE CALC	ULATIONS =	\$130.00		
Applicant claims small entity st	\$						
- (1400 00 (14)				SUBTOTAL =	\$130.00		
Processing fee of \$130.00 for furr 1.492(i)).	hishing the English translation	ı later than 30 montns from th	e earliest priority date	e (37 CFR +	\$		
			TOTAL NATI	ONAL FEE =	\$130.00		
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property.							
			TOTAL FEES E	NCLOSED =	\$130.00		
					Amount to be refunded:	\$	
A short the second of	100.00				charged:	\$	
<ul> <li>a.  A check in the amount of \$ 130.00 to cover the above fees is enclosed.</li> <li>b.  Please charge my Deposit Account No in the amount of \$ to cover the above fees.</li> </ul>							
A duplicate copy of this sheet is enclosed.  c.   The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account							
No. <u>06-0916</u> . A duplicate copy of this sheet is enclosed.							
<ul> <li>d.          Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.     </li> </ul>							
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.							
SEND ALL CORRESPONDENCE TO:							
Finnegan, Henderson, Farabow, 0 901 New York Avenue, N.W.		•.					
Washington, DC 20001-4413	Emest F, Chapman Reg. No. 25,961						
DATED: May 8, 2007							



## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450

P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.

FIRST NAMED APPLICANT

ATTY. DOCKET NO.

10/578,077

Yoshio Miki

081780031

INTERNATIONAL APPLICATION NO.

PCT/JP04/16805

I.A. FILING DATE

PRIORITY DATE

11/05/2004

11/05/2003

22852 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413

RECEIVED

MAR 1 4 2007

**CONFIRMATION NO. 3057 371 FORMALITIES LETTER** 

"OC000000022815559"

Date Mailed: 03/09/2007

FINNEGAN, HENDERSON. FARABOW. GARRETT AND DUNNER, LLP

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 05/03/2006
- English Translation of the IA filed on 05/03/2006
- Copy of the International Search Report filed on 05/03/2006
- Information Disclosure Statements filed on 02/20/2007
- Biochemical Sequence Diskette filed on 05/03/2006
- Request for Immediate Examination filed on 05/03/2006
- U.S. Basic National Fees filed on 05/03/2006
- Priority Documents filed on 05/03/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

• \$130 Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <a href="http://www.uspto.gov/ebc.">http://www.uspto.gov/ebc.</a>

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

LAMONT M HUNTER

Telephone: (703) 308-9140 EXT 201

#### PART 1 - ATTORNEY/APPLICANT COPY

		•
U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/578,077	PCT/JP04/16805	081780031

FORM PCT/DO/EO/905 (371 Formalities Notice)